

Health Advisory: Recommended Suspension of Routine Use of 3rd and 4th Doses of Pneumococcal Conjugate Vaccine (Prevnar®)

March 3, 2004

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Health Advisory
March 3, 2004

**FROM: RICHARD C. DUNN
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SUBJECT: CDC Recommends Suspension of the Routine Use of the Third and Fourth Doses of Pneumococcal Conjugate Vaccine (Prevnar®)

On March 2, 2004, the Centers for Disease Control and Prevention (CDC) issued a recommendation stating that all health-care providers should temporarily suspend routine use of both the third and fourth doses of pneumococcal conjugate vaccine (PCV7). Children at increased risk of severe disease should continue to receive the full, routine, four-dose series.

CDC took the action in consultation with the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP), to most effectively use the limited, available doses until the manufacturer can restore full production. Wyeth Vaccines, the sole manufacturer in the United States, markets PCV7 under the trade name Prevnar®.

"CDC is concerned anytime children are not able to receive all of the recommended doses of a recommended vaccine," said Dr. Steve Cochi, acting director for the CDC's National Immunization Program. "Delaying the third and fourth doses of this important vaccine is not ideal; however, it is important to take steps to assure all children receive some protection with at least two doses of vaccines."

CDC had previously recommended that health-care providers temporarily suspend routine use the fourth dose. Since that recommendation was issued, PCV7 production has been much less than had been expected and shipments have been further delayed, resulting in shortages of vaccine. Widespread shortages may now continue beyond this summer.

"Four doses of PCV7 provide the best protection, but children who have received three doses should also have a very high level of protection," said Dr. Cochi. "Children who have had two doses should also have some protection, but the exact level is unknown."

Children whose third and fourth doses are delayed should receive the missed doses on their first visit to a healthcare provider after supplies return to normal. Healthcare providers should keep track of children who are not able to get all of the recommended doses of the vaccine and then contact those patients when they receive adequate supplies of vaccine.

Children with certain health conditions, such as sickle cell anemia or immune system disorders, are at increased risk of severe disease and should continue to receive the full, routine, four-dose series.

The vaccine is normally recommended for young children in a four-dose schedule: one dose at 2 months, at 4 months, and at 6 months, and one dose between 12 and 15 months. This recommendation suspends the third and fourth doses usually administered at 6 months and between 12 and 15 months for healthy children. PCV7 is not routinely recommended for children 2 years of age or older.

The vaccine can help prevent serious pneumococcal diseases, such as meningitis and blood infections. Pneumococcal infection can cause serious illness and even death. Invasive pneumococcal disease is the leading cause of bacterial meningitis in the United States. Children under two years of age are at highest risk. Before a vaccine was available, each year pneumococcal infection caused more than 700 cases of meningitis, 13,000 blood infections and about 5 million ear infections.

WHY YOUR CHILD MAY HAVE TO WAIT TO GET HIS OR HER THIRD OR FOURTH DOSE OF PREVNAR[®] VACCINE: FACTS FOR PARENTS

- At this time, there is a low supply of pneumococcal conjugate vaccine, also called Prevnar[®]. This vaccine protects children against serious disease and death caused by bacteria called *Streptococcus pneumoniae*.
- Because of low supplies, it is important to take steps to make sure all children get some Prevnar[®] vaccinations.
- While supplies are low, your healthcare provider has been asked to wait to give most children their 3rd and 4th doses of Prevnar[®] vaccine. Children whose 3rd or 4th dose is delayed should receive it on their first doctor's visit after supplies return to normal.
- Four doses of Prevnar[®] vaccine provide the best protection, but your child will still have a very high level of protection if he or she has had three doses. Children who have had two doses of Prevnar[®] should also have some protection, but the exact level is not known.
- Children with certain health conditions, like sickle cell anemia or immune system disorders, are more prone to *Streptococcus pneumoniae* infections. Such children should still get all four shots.
- By temporarily not giving the third and fourth doses of Prevnar[®] vaccine to healthy children, healthcare providers will save many doses of vaccine. As a result, there should be enough vaccine for all children to get at least two doses.
- Experts do not know exactly when supplies of Prevnar[®] vaccine will be back to normal. They expect supplies to be limited for several more months.

More Information

Vaccinating your children is one of the most important ways you can protect them from infectious diseases. Children should get certain vaccines when they reach certain ages, according to the recommended immunization schedule. Vaccinating children on time helps to give them the best protection possible.

Prevnar[®] is one of the vaccines in the recommended childhood immunization schedule. This vaccine protects against disease caused by bacteria called *Streptococcus pneumoniae*. This bacteria can cause serious illness, including meningitis (an infection of the covering of the brain), blood stream infections, and infection of the lungs. *Streptococcus pneumoniae* can infect anyone, but is most likely to cause serious infection in infants and in children with certain medical conditions. Infants and toddlers should usually get four doses of Prevnar[®], one dose at 2 months, 4 months, 6 months, and 12-15 months of age.

Once in a while in the U.S., we do not have enough vaccine to vaccinate all children on time. When this happens, doctors may need to make temporary changes in their patient's vaccination schedules. This is done to help save vaccines and ensure that the children most in need of protection get it. In February 2004, doctors and other experts became worried that the supply of Prevnar[®] would be low for several months.

Steps have been taken by the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC) in an attempt to prevent healthcare providers from running out of Prevnar[®] vaccine. These steps have worked so far, but more needs to be done.

CDC, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) have decided to recommend that doctors continue to give all children the first two doses of Prevnar[®] vaccine but that they stop, for now, giving healthy children the third and fourth doses scheduled to be given at 6 months and 12-15 months of age.

Delaying the third and fourth doses of Prevnar[®] is not ideal. However, this step will help make sure that all children get at least two doses of the vaccine. Doctors and other experts believe that giving all children two vaccinations will result in less disease than if some children get 3 or 4 doses while others get none.

Children with certain health conditions that make them more prone to *Streptococcus pneumoniae* infections should still get all four shots. Your healthcare provider can help determine if your child has a health condition that puts him or her at increased risk.

If we did not delay the 3rd and 4th doses of Prevnar[®] for most children, there would probably be widespread, serious shortages. If this happened, some children might not get any doses of the vaccine. By not giving the third and fourth doses routinely, we expect to save a large amount of vaccine so that all children will be protected with at least two doses.

CDC, AAP, and AAFP continue to watch the vaccine supply situation closely. No other routine childhood vaccines are in short supply so your child should continue to receive all the other vaccines on the normal schedule. More information about vaccine shortages is available at www.cdc.gov/nip/news/shortages. Information about what vaccines your child should receive can be found at www.cdc.gov/nip/kidstuff.

For more information, visit www.cdc.gov/nip, or call the Immunization Program at the Missouri Department of Health and Senior Services (DHSS) at (800) 219-3224. Information can also be obtained from the CDC National Immunization Information Hotline at (800) 232-2522 (English), (800) 232-0233 (Español), or (800) 243-7889 (TTY).